

Ashley Lee: Factors Affecting Prosthesis Life in Tracheoesophageal Speech

Factors Affecting Voice Prosthesis Life in Tracheoesophageal Speech

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Dedication

This thesis is dedicated to my parents, D. Curtis and Toni L. Lee, and my boyfriend, Scott Dugan, for all of their support.

Acknowledgments

I would like to acknowledge my defense committee members, Dr. Michael Trudeau, Dr. Janet Weisenberger, and Dr. Amit Agrawal for their time and suggestions. I would like to thank Dr. Michael Trudeau for teaching me everything I know about tracheoesophageal speech after a total laryngectomy, I would like to thank Dr. Janet Weisenberger for pairing me with Dr. Michael Trudeau, and I would like to thank Dr. Amit Agrawal for his surgical expertise.

Abstract

Persons with advanced cancer of the larynx or pyriform sinuses frequently undergo laryngeal amputation (laryngectomy) to remove the tumor. Among the sequelae to this surgery are permanent diversion of the lower airway to a tracheostoma at the base of the neck with loss of the upper airway for respiration and olfaction, maintenance of oral swallowing (but altered by loss of the larynx and alteration of the upper esophageal sphincter), and loss of voice (Stemple, Glaze, & Klaben, 2000).

There are three primary methods for voice restoration following total laryngectomy: esophageal speech, speech with an artificial vibratory source (a.k.a. electrolarynx), and tracheoesophageal (TE) speech, which requires a voice prosthesis (v.p.) (Stemple, Glaze, & Klaben, 2000). The latter is the focus of the present study.

Since the introduction of the first effective v.p. in 1980 (InHealth Technologies ENT Product Catalog, 2005), there has been a steady increase in the variety of designs of prostheses available for use. This increase in variety raises questions about which design is “best” or what criteria should be employed in selecting v.p.s.

The study is a chart review of a 29 patients with total laryngectomy and primary TEP who have been in recovery for at least one year (time frame, 2003-2004). The goal is to identify changes in selected v.p.s and reasons for such changes in the first year post-surgery.

The primary trend was a reduction in v.p. length over the first year. A second surprising trend was the relatively short useful life of the clinician-inserted v.p.s. A third trend was the pervasive presence of candida colonization of voice prostheses (a condition which produces premature breakdown of the v.p. valve).

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Introduction

The larynx is important both in the protection of the airway and in phonation; however, due to its mucosal lining the larynx is susceptible to cancer. The total laryngectomy has played a major role in the treatment of laryngeal cancer since 1873 (Singer, 1983). With laryngeal amputation the patient experiences a consequent loss or impairment of several important functions including respiration, deglutition, olfaction, phonation, and protection of the airway. The surgeon removes the entire larynx, the inferior and superior muscular attachments, the hyoid bone, the extrinsic strap muscles, and possibly the upper two or three tracheal rings (Stemple, Glaze, & Klaben, 2000). The surgeon then anchors the trachea to the base of the neck creating a permanent opening called the tracheostoma (see Appendix A). Because of this alteration, respiration no longer occurs through the upper airway, but through the tracheostoma. The surgeon also insures the integrity of the connection between the hypopharynx and the upper esophagus (Salmon & Mount, 1991).

Both phonation and protection of the airway are disrupted when the larynx is removed. The production of voice requires a vibratory body and a power source. The vibratory body in a person with a fully intact vocal tract is the vocal folds which are housed in the larynx, and the power source is pulmonary or exhaled air from the lungs (Lombard, 1996). Three options for voice restoration, esophageal speech, speech with an artificial larynx, and tracheoesophageal speech, are plausible solutions for the aphonia occurring after total laryngectomy (Stemple, Glaze, & Klaben, 2000). However, all three methods have advantages and disadvantages, and the goal of the speech-language pathologist and otolaryngologist is to find the method best suited for the patient.

A major advantage of esophageal speech is the cost aspect. This technique does not require expensive devices and prostheses. However, its success rate of acquiring production is not very high because to produce esophageal speech, the patient must relax the esophageal sphincter volitionally (ORL – Oto Rhino Laryngology Web, 2002). The resting state of a normal esophageal sphincter is tonic, and unless the sphincter has been damaged and weakened, due to a total laryngectomy for instance, esophageal speech may not be established. Esophageal speech requires patience and practice as mastery of this form of speech can entail six months or more of therapy (WebWhispers.org, 2004). For more information on esophageal speech see <http://www.webwhispers.org/pages/library/esophageal.htm>.

Speech via an electrolarynx has its advantages and disadvantages as well. The major advantage is that basic speech is learned quickly by most patients and does not interfere in learning other forms of alaryngeal speech. On the other hand, disadvantages include the mechanical sound, a dependence on batteries, and the interference of the loudness of voice due to certain patient conditions. Severe post-surgical scarring and radiation therapy with associated edema may interfere with transfer of sound into the resonant cavities of the vocal tract (ORL – Oto Rhino Laryngology Web, 2002).

In order for the patient to obtain tracheoesophageal (TE) speech, the surgeon must create a fistula or puncture through the common walls of the trachea and esophagus either at the time of the total laryngectomy (primary puncture) or at some subsequent time (secondary puncture). A voice prosthesis (v.p.) is inserted into the fistula, and the patient is able to speak by occluding the tracheostoma diverting pulmonary air from the lungs

through the v.p. into the upper esophagus where tissue vibrates to generate the sound source for speaking (InHealth Technologies, 2000-2005)(see Appendix B). The v.p. is important not only to allow the air to flow from the trachea to the esophagus for voice production, but also to maintain the puncture and to prevent esophageal leakage into the trachea during swallowing (Blom, Information Data Sheet).

The development of voice prostheses has improved immensely over the past seventy-four years from a simple goose quill to a silicone one-way slit valve (Singer, 1983), and today, speech-language pathologists and otolaryngologists face a myriad of decisions when assisting the laryngectomee. These decisions greatly affect the restoration of voice and can prevent isolation and depression for the post-laryngectomy patient. Length, diameter, type of retention collar, method of insertion, and the patient's ability to care for the prosthesis are among the factors the speech-language pathologist and otolaryngologist must consider in establishing TE speech for a patient. The wrong decision results in an inability to communicate vocally. The wrong prosthesis may also pose a dangerous risk of pneumonia (through chronic aspiration of fluids into the airway via the prosthesis) or of airway compromise associated with the prosthesis occupying space in the tracheostoma or actually dislodging and falling into the trachea (Laccourreye, et al., 1997).

The idea that the upper esophageal sphincter, or pharyngoesophageal (PE) segment, could act as a sound source and the body of the esophagus as the air reservoir/power source for speech came about in 1922. Since then, prostheses have evolved from simple goose quills to one-way valves made of medically high grade silicone. In 1931, a post-laryngectomy patient pierced his own neck with a red hot ice

pick establishing a tracheal shunt, and he used a goose quill to maintain the puncture. Not until 1972 was the first commercially available v.p. developed, the Voice Bak. It was expensive, awkward, and required regular mechanical maintenance (Singer, 1983). Eight years later Blom and Singer developed the original duckbill v.p. that has become the international standard for voice restoration over the past 25 years (InHealth Technologies ENT Product Catalog, 2005).

One important distinction in the current generation of v.p.s is based on who is responsible for changing/replacing improperly functioning devices. Clinician-inserted and patient-inserted devices serve the same purposes: to maintain the puncture, allow air to flow from the trachea to the esophagus for voice production, and to prevent esophageal leakage into the trachea during swallowing. Both voice prostheses are cylindrical in shape and consist of a neck strap(s), a retention collar, and a slit, hinged, or balled valve. Both the neck strap(s) and retention collar help to keep the prosthesis in place. However, the neck strap(s) is taped to the skin of the neck, and the retention collar grips the inside of the esophageal wall to prevent dislodgment. The valve opens under positive pressure as air enters the esophagus, and it closes by elastic recoil (Stemple, Glaze, & Klaben, 2000).

The patient-inserted prosthesis can be removed, cleaned, and inserted by the patient. However, the clinician-inserted v.p. is a more recent development that was created in hopes of solving self-care issues. They contain larger tracheal and esophageal retention collars requiring a significantly greater effort to remove and replace the v.p. (Stemple, Glaze, & Klaben, 2000). Although these v.p.s are purported to be more durable (lasting approximately 6 to 12 months), they are also more expensive. As of

March 1, 2005, Inhealth's patient-inserted duckbill v.p. was only 27 dollars, and the low pressure v.p. was only 43 dollars. However, Inhealth's clinician-inserted v.p. was 125 dollars (Inhealth Technologies Patient Price List, 2005), and as of February 1, 2005, Atos's clinician-inserted v.p. was 199 dollars (Atos Medical price list, 2005). As of 7/1/05, Medicare's reimbursement for all voice prostheses, regardless of actual cost, was \$88.09. Aetna's reimbursement was \$78.69, United Health Care's reimbursement was \$136.00, and Medical Mutual's reimbursement was \$74.00 (Billing Information on Patient Records).

The duckbill, low-pressure, and ultra-low resistance v.p.s are three styles of patient-inserted devices (see Appendix C). The duckbill v.p. is a 16 or 20 French (Fr.) silicone, one-way slit valve that is available in 9 standard lengths ranging from 6mm to 28mm. Patients may also order custom lengths if needed. Out of the three patient-inserted devices, the duckbill extends the farthest into the esophagus and would not be well suited for a patient whose esophageal lumen at the level of the TEF is too narrow to accommodate this device (Stemple, Glaze, & Klaben, 2000).

The low pressure v.p. is also available in 9 standard lengths ranging from 6mm to 28mm and in 2 diameters of 16 & 20 Fr. (Inhealth). The low-pressure v.p. has a recessed valve and a low profile tip making it more difficult to insert the v.p. into the fistula. This is why the Blom-Singer Gel Cap Insertion System was invented (Stemple, Glaze, & Klaben, 2000).

Finally, the ultra-low resistance v.p. was available in 7 standard lengths ranging from 6mm to 22mm and in 2 diameters of 16 & 20 Fr. (Bivona), and this particular device contains a thinner retention collar and can be inserted and removed easier. This is

beneficial to patients with a sensitive TEF (Stemple, Glaze, & Klaben, 2000). Bivona ceased manufacture of all v.p.s in late 2004.

Atos' Provox II and Inhealth's Indwelling are two styles of clinician-inserted devices (See Appendix D). The Provox II is a second-generation prosthesis that was introduced in 1997. It contains several valuable features including low airflow resistance, easy maintenance, safe placement, detectable in x-ray, and high success rate. It is a 21 Fr. silicone one-way valve that is available in 6 standard lengths ranging from 4.5mm to 15mm and may either be inserted retrograde using the Provox Guidewire or preferably antegrade using the single-use insertion tool (Atos Medical Catalog, 2005).

The Indwelling v.p. is another clinician-inserted device that is also intended for patients who have self-care issues, such as an inability to perform the routine removal and insertion needed to clean the v.p. It is a 20 Fr. silicone one-way valve available in 8 standard lengths ranging from 6mm to 25mm. Patients may also order custom lengths if needed (Inhealth Technologies ENT Product Catalog, 2005) (see Table 1 for a complete breakdown of v.p.s in the present study).

The development of voice prostheses and tracheoesophageal speech has improved immensely over time. Yet, there are still many potential complications. Complications in this instance are defined as anything that prevents, delays, or interferes with voice restoration via tracheoesophageal speech. These complications can be broken down into patient-related issues (Leder, et al., 1995) and prosthesis-related issues (Mäkitie, et al., 2003). Patient-related issues include self-care issues (Leder, et al., 1995) and related physical issues, such as pharyngoesophageal spasm, radiation-induced fibrosis, pneumonia, emphysema, recurrent cancer, and dysphagia.

Self-care issues involve removing, cleaning, and reinserting the v.p., and these issues are usually addressed when the patient is seen for the first visit with the speech-language pathologist. The removal of the prosthesis is accomplished by firmly grasping the v.p. and pulling forward. The patient or clinician should then immediately insert a catheter or tracheoesophageal puncture dilator to prevent aspiration and stenosis. Once the prosthesis is cleaned or to be replaced according to the instructions given by the manufacturer, the v.p. can be reinserted often with the Blom-Singer Gel Cap Insertion System (Stemple, Glaze, & Klaben, 2000).

Another patient-related issue is the ability to readily occlude the stoma. The tracheostoma valve is an optional device that may be used to eliminate this problem and is also beneficial for many patients who are required to use both hands while working. The tracheostoma valve consists of two components, a housing collar and a valve. The housing collar is taped and glued to the tissue surrounding the stoma and may not be sufficient for patients with sunken stomas or uneven skin tissue surrounding the stoma. This patient may not have an adequate skin surface for collar adhesion. When the patient develops sufficient pulmonary air pressure to produce speech, the valve will close, occluding the stoma and directing air into the v.p. (Stemple, Glaze, & Klaben, 2000).

The patient-related issue of pharyngoesophageal (PE) spasm is a complication in voice rehabilitation via tracheoesophageal speech that appears to be caused by reflexive contraction of the cricopharyngeal and constrictor muscles when the mid-esophagus is distended with air (Quinn, 1996). There are three options for recovery from PE spasm. The patient can do nothing, because PE spasm is not a health hazard. The patient can use a chemical (Botox injection) or surgery (PE myotomy) to weaken the

sphincter, or they can have the TEF resized to accommodate a larger diameter v.p. The higher volume of air flow may assist the patient in managing the spasm (Stemple, Glaze, & Klaben, 2000).

Another physical issue that affects the patient's ability to produce voice is radiation induced fibrosis. This is one of the various side effects associated with the use of radiation as an additional treatment before or after surgery. Radiation is usually used to shrink a lesion prior to surgery or to destroy cancerous cells not detected post-surgery. In the latter case, patients obtain the best results if treatments begin 6 weeks following surgery and end within 100 days of surgery (Stemple, Glaze, & Klaben, 2000).

Prosthesis-related issues break down into two subcategories, leakage around the v.p. and leakage through the v.p. (Mäkitie, et al., 2003). Leakage around the device usually means that the lumen of the fistula or puncture has enlarged, and it no longer fits snugly around the shaft of the v.p. This complication may have resulted spontaneously over time, or it may have resulted from wearing a v.p. that is too long. When a v.p. is too long, the act of swallowing may push down on the esophageal end momentarily widening the diameter of the fistula. This momentary widening may eventually enlarge the diameter of the fistula causing further complications in the future (Salmon & Mount, 1991).

On the other hand, leakage through the v.p. may either be the result of normal wear and tear or candida colonization. Candida colonization is the deterioration of silicone caused by the candida organism (Salmon & Mount, 1991). The risk of candida colonization may increase when the patient has had radiation treatment or frequent use of antibiotics (The Milton J. Dance, Jr. Head & Neck Rehabilitation Center, 1999).

Complications, such as an inability to readily occlude the stoma, PE spasm, radiation-induced fibrosis, and candida colonization may be inevitable; however, there are still many unanswered questions. A few of these unanswered questions are:

- 1) How does v.p. length change in the first year of recovery?
- 2) How does v.p. diameter change in the first year of recovery?
- 3) How many patients switch from a patient-inserted v.p. to a clinician-inserted v.p. and vice versa in the first year of recovery?
- 4) Are there gender-related differences in speech rehabilitation in the first year of recovery?
- 5) Do clinician-inserted v.p.s really last longer than patient-inserted v.p.s?
- 6) How long do these v.p.s last before they wear out?
- 7) Are there factors in patient speech rehabilitation more commonly found following radiation?

Past studies have addressed some of these issues, but they have primarily focused on one or two types of v.p.s or only one manufacturer. Laccourreye, et al. focused on the Provox clinician-inserted v.p. (Laccourreye, et al., 1997), and Leder and Sasaki only focused on Inhealth's v.p.s (Leder & Sasaki, 1995). However, the present study focuses on five different types of v.p.s from three different manufacturers and addresses these issues in hopes of gaining a better understanding in the future.

Materials and Methods

Data Collection Procedure

The present study is a retrospective charts review of all 48 patients with total laryngectomy and TEP treated at the Arthur G. James Cancer Hospital and Richard Solove Research Institute at the Ohio State University from January 2003 to the end of 2004. Information was gathered from the voice therapy and physician notes and compiled into an Excel spreadsheet. The data consist of identification number, patient initials, date of birth, date of laryngectomy, related surgeries including flap reconstruction, pre or post-operation radiation treatment, date of voice therapy session, type and manufacturer of v.p., length of v.p., diameter of v.p., the patient's ability to care for the v.p., reason for altering the v.p., competency in tracheoesophageal speech, related health conditions, related health treatment, insurance, physician, and speech-language pathologist. The goal is to identify trends that may be beneficial in the clinical decision making process.

Participants

The data collected consists of 36 men and 12 women with an age range from 32 years, 5 months to 93 years, 4 months at the time of surgery. Most patients (87%) were fitted with a v.p. between 17 and 60 days following total laryngectomy. The earliest initial speech therapy session occurred 8 days after total laryngectomy, and the latest was at 235 days, with a mean period of 47.5 days and a median of 32 days. In four cases the surgeon inserted the v.p. at the time of the laryngectomy.

Tracheoesophageal Prostheses

Essentially two types of voice prostheses, patient-inserted and clinician-inserted devices, were used. Both are silicone one-way valves that serve the same purposes, to maintain the puncture, allow air to flow from the trachea to the esophagus for voice production, and to prevent esophageal leakage into the trachea during swallowing (Blom, Information Data Sheet). However, the patient-inserted prosthesis can be removed, cleaned, and inserted by the patient, but the clinician-inserted v.p. stays in place until a problem persists. Then, the patient must see a clinician to remove and replace the device (Stemple, Glaze, & Klaben, 2000).

The duckbill, low-pressure, and ultra-low resistance are three styles of patient-inserted devices. The duckbill v.p. is a 16 or 20 Fr. silicone, one-way slit valve that is available in 9 standard lengths ranging from 6mm to 28mm. Patients may also order custom lengths if needed. Out of the three patient-inserted devices, the duckbill extends the farthest into the esophagus and would not be well suited for a patient whose esophageal lumen at the level of the TEF is too narrow to accommodate this device (Stemple, Glaze, & Klaben, 2000).

The low pressure v.p. is also available in 9 standard lengths ranging from 6mm to 28mm and in 2 diameters of 16 and 20 Fr. (Inhealth). The low-pressure v.p. has a recessed valve and a low profile tip making it more difficult to insert the v.p. into the fistula. This is why the Blom-Singer Gel Cap Insertion System was invented (Stemple, Glaze, & Klaben, 2000).

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device contains a thinner retention collar and can be inserted and removed easier. This is beneficial to patients with a sensitive TEF (Stemple, Glaze, & Klaben, 2000). Bivona ceased manufacture of all v.p.s in late 2004.

Atos' Provox II and Inhealth's Indwelling are two styles of clinician-inserted devices. The Provox II is a second-generation prosthesis that was introduced in 1997. It contains several valuable features including low airflow resistance, easy maintenance, safe placement, detectable in x-ray, and high success rate. It is a 21 Fr. silicone one-way valve that is available in 6 standard lengths ranging from 4.5mm to 15mm and may either be inserted retrograde using the Provox Guidewire or preferably anterograde using the single-use insertion tool (Atos Medical Catalog, 2005).

The Indwelling v.p. is another clinician-inserted device that is also intended for patients who have self-care issues, such as an inability to perform the routine removal and insertion needed to clean the v.p. It is a 20 Fr. silicone one-way valve available in 8 standard lengths ranging from 6mm to 25mm. Patients may also order custom lengths if needed (Inhealth Technologies ENT Product Catalog, 2005).

Results

Participants

The present study was a retrospective charts review of 48 patients with total laryngectomy and TEP who had completed one year of recovery. Of these 48 patients, 19 were lost to follow-up either because of a referral to another facility closer to the patient's home (6), a TEP closure (10), or ceased service at the James Cancer Hospital (3). Of the remaining 29 patients, 27 had completed at least 12 months of recovery, and 2 had TEP closure just prior to 12 months (range 9-11 months). This latter group was

retained for data analysis, as their experience basically reflected the first year of recovery. Of these 29 patients, there were 20 men and 9 women with an age range from 41 years, 11 months to 81 years, 6 months. The mean age of men was 60 years with a range of 41 years, 11 months to 81 years, 6 months, and the mean age of women was 65 years with a range of 51 years, 1 month to 79 years, 8 months (See Table 2). Most patients (82.8%) were fitted with a v.p. between 17 and 53 days following total laryngectomy. The earliest v.p. fitting was performed 8 days after total laryngectomy, and the latest was at 263 days, with a mean period of 55 days and a median of 34 days.

Prosthesis Lifetime

Twenty-seven of the 29 patients who were available for long-term follow-up required TE prosthesis resizing. The amount of change in v.p. length from the initial fitting to the end of the first year ranged from 0 to 12 mm. Twenty-five patients required replacement prostheses which were shorter, 1 patient required replacement prostheses which were longer, and 2 patients' prostheses remained the same in length from the initial fitting to the end of the first year. The remaining patient had 4 therapy sessions in which the patient's prosthesis remained the same in length from initial fitting until closure of the TEF and had 5 sessions in which the patient required a replacement prosthesis which was shorter from re-opening of the TEF to the end of the first year.

Over the course of the first year, there was a strong tendency for refitting with a shorter v.p. At initial fitting, the average v.p. length was 16.28 mm. The range was 8 mm to 28 mm, the mode was 18 mm, and the standard deviation was 4.68 mm. At the end of the first year, the average v.p. length was 10.91 mm. The range was 4.5 mm to 18 mm, the mode was 10 mm, and the standard deviation was 3.2 mm (See Table 3).

Twenty-five of the 29 patients' prostheses were 16 Fr. in diameter at the initial fitting, and only 4 of the 29 patients' prostheses were 20 Fr. (InHealth) or 21 Fr. (Atos) at initial fitting. However, 16 of the 29 patients were using a 16 Fr.v.p. at the end of the first year, and 13 of the 29 patients were using a 20 or 21 Fr.v.p. at the end of the first year. At the initial post-operative session, more patients used 16 Fr.v.p.s than 20 French. This reflects the surgeon's decision on tracheoesophageal puncture diameter and the initial use of the Provox 2 (21 Fr.) (See Table 4).

Of the 29 patients available for long-term follow-up, three patients required at least one re-puncture, and TEP closure was evident in 2 patients just prior to 12 months. All three re-punctures occurred following patient report of difficulty in inserting the v.p. after cleaning. One of these three patients switched from using a patient-inserted v.p. before re-puncture to using a clinician-inserted v.p. after re-puncture. The remaining two patients with re-puncture continued to use a patient-inserted device after re-puncture. The patient who switched from a patient-inserted device to a clinician-inserted device and one of the patients who continued using a patient-inserted device were able to obtain at least functional TE speech. Functional, in this case, refers to the ability to produce understandable sentence-length adult utterances. However, the other patient who continued with a patient-inserted device was unable to obtain moderate TE speech until the very last session. This patient was sidelined not only in TE speech but also in the use of an electrolarynx due to a pharyngocutaneous fistula, neck edema, and pharyngoesophageal spasm.

Of the 2 patients with TEP closure just prior to the first year of recovery, only 1 was able to obtain phrase length to conversational TE speech at some point in the first

year of recovery. It is unknown why TEP closure occurred in this patient. However, the other patient with TEP closure was hospitalized with recurrent cancer and could no longer care for the v.p. This patient was unable to obtain phrase length to conversational speech in the first year of recovery because of radiation edema and PE spasm.

A total of 104 v.p.s were removed and/or replaced in the 29 patients available for long-term follow-up. Thirty-three of these v.p.s were removed and replaced, because the v.p. had worn out. Of the 33 v.p.s that had worn out, 28 had been colonized with candida, and the valve broke in 5 v.p.s. Seven of the 104 v.p.s were replaced by the speech-language pathologist (SLP), because the old v.p. had either been aspirated, lost, protruded into the airway inappropriately, or fell out. It is unknown from the chart notes why 10 of the 104 v.p.s were removed and replaced by the SLP. Manufacturer, type, length, and diameter remained the same from the previous therapy session, and the reason for v.p. replacement was not indicated in the chart. Thirty-seven of the 104 v.p.s were removed and replaced with a shorter v.p. Nineteen of the 37 v.p.s were not only replaced with a shorter v.p., but also were replaced with a different type of v.p. Seven patient-inserted devices were replaced with clinician-inserted devices, and the remaining 12 patient-inserted devices were replaced with a different type of patient-inserted device. Eight of the 104 v.p.s were removed and replaced with a longer v.p. Five of the 10 v.p.s were not only replaced with a longer v.p., but were also replaced with a different type of v.p. Two ultra-low resistance v.p.s were replaced with low pressure v.p.s, 1 low pressure v.p. was replaced with an ultra-low resistance v.p., 1 low pressure v.p. was replaced with a duckbill v.p., and an Atos clinician-inserted v.p. was replaced with an Inhealth clinician-inserted v.p. The remaining 9 of the 104 v.p.s were replaced because of the

decision either to use a different type of v.p. or a different manufacturer. Four patient-inserted v.p.s were replaced with a different type of patient-inserted v.p., 3 clinician-inserted v.p.s were replaced with patient-inserted v.p.s, 1 patient-inserted v.p. was replaced with a clinician inserted v.p., and 1 Inhealth clinician-inserted v.p. was replaced with a Provox clinician-inserted v.p.

Sixty-six of the 104 v.p.s that were removed (10 duckbill, 46 low pressure, & 10 clinician-inserted) were Inhealth prostheses. Thirty-three (22 ultra-low resistance & 11 duckbill) were Bivona prostheses, and the remaining 5 prostheses were Atos' Provox. The average lifetime of the clinician-inserted Atos Provox was 80.8 days, of the patient-inserted Inhealth duckbill was 74.7 days, of the clinician-inserted Inhealth Indwelling was 74.7 days, of the patient-inserted Inhealth low pressure was 58.87 days, of the patient-inserted Bivona ultra-low resistance was 44.68 days, and of the patient-inserted Bivona-duckbill was 44.18 days.

In summary, the sample contained 89 patient-inserted and 15 clinician-inserted v.p.s. The average number of days between fittings of the clinician-inserted v.p.s was 76.7 days. The range was 14 to 220 days, the median was 62 days, and the standard deviation was 55.11 days. The average number of days between fittings of the patient-inserted v.p.s. was 55.33 days. The range was 1 to 338 days, the median was 42 days, and the standard deviation was 54.6 days (See Table 5). This indicates a relatively short useful life of the clinician-inserted v.p.s.

At initial fitting, 27 of the 29 patients used a patient-inserted device, and only 2 used a clinician-inserted device. However, while most patients continued with patient-inserted v.p.s there was a trend to increase the use of clinician-inserted devices in the first

year. At the end of the first year, 22 patients used patient-inserted devices, and 7 used clinician-inserted devices (See Table 6).

Twenty-eight (27%) of the 104 v.p.s were removed because of candida colonization, including 16 Inhealth prostheses (8 low pressure, 4 duckbill, & 4 clinician-inserted), 8 Bivona prostheses (7 ultra-low resistance & 1 duckbill), and 4 Atos clinician-inserted (Provox) prostheses. Seven of 22 ultra-low resistance v.p.s (32%), 1 of 11 Bivona duckbill v.p.s (9%), 4 of 10 Inhealth duckbill v.p.s (40%), 8 of 46 Inhealth low pressure v.p.s (17%), 4 of 10 Inhealth clinician-inserted v.p.s (40%), and 4 of 5 Atos clinician-inserted (Provox) v.p.s (80%) were colonized with *Candida Albicans* (See Table 7).

Complications

As mentioned previously, complications, in this instance, refer to anything that prevents, delays, or interferes with voice restoration via tracheoesophageal speech. The complications of most concern in the present study were patient-related issues, such as an inability to readily occlude the stoma, pharyngoesophageal (PE) spasm, radiation-induced fibrosis, pneumonia, emphysema, recurrent cancer, and dysphagia, and prosthesis-related issues, such as candida colonization.

Of the 29 patients available for long-term follow-up, 23 were able to obtain at least phrase length to conversational speech at some point in the first year of recovery. Of the remaining 6 patients who were not able to obtain phrase length to conversational speech in the first year of recovery, 2 had difficulty with stoma occlusion, TEP closure was evident in 1 just prior to the first year, 1 had extensive pharyngeal and esophageal reconstruction and dysphagia, and it is unknown why the remaining patient could not

produce conversational TE speech. Of the 2 who had difficulty with stoma occlusion, 1 also acquired neck edema, and the other acquired PE spasm and dysphagia. The patient with TEP closure just prior to the first year of recovery was hospitalized with recurrent cancer and could no longer care for the v.p. This patient was unable to obtain phrase length to conversational speech in the first year of recovery because of radiation edema and PE spasm.

Of the 29 patients available for long-term follow-up, 7 had difficulty in stoma occlusion at some point in the first year of recovery, and PE spasm was evident in 8. Radiation-induced fibrosis, neck edema, mandibular and peristomal edema, post-radiation erythema, and/or tissue devascularization was also evident in 8. Of the 29 patients, 1 had pneumonia, 3 developed recurrent cancer, 5 had some form of dysphagia, and 13 patients had candida colonization on their v.p. at some point in the first year of recovery.

Discussion

The present study was performed to gain a better understanding of how v.p. length changes in the first year of recovery, how v.p. diameter changes in the first year of recovery, how many patients switch from a patient-inserted v.p. to a clinician-inserted v.p. and vice versa in the first year of recovery, whether there are gender-related differences in speech rehabilitation in the first year of recovery, whether clinician-inserted v.p.s really last longer than patient-inserted v.p.s, how long these v.p.s last before they wear out, and whether there are factors in patient speech rehabilitation more commonly found following radiation.

How does prosthesis length change in the first year of recovery? The primary trend in the present study identified a reduction in v.p. length over the first year. At the end of the first year, 25 of the 29 patients available for long-term follow-up required replacement v.p.s which were shorter than at initial fitting. At initial fitting, the average v.p. length was 16.28 mm. The range was 8 mm to 28 mm, the mode was 18 mm, and the standard deviation was 4.68 mm. At the end of the first year, the average v.p. length was 10.91 mm. The range was 4.5 mm to 18 mm, the mode was 10 mm, and the standard deviation was 3.2 mm (See Table 3).

How does prosthesis diameter change in the first year of recovery? Twenty-five of the 29 patients' prostheses were 16 Fr. in diameter at the initial fitting, and only 4 were 20 Fr. (InHealth) or 21 Fr. (Atos) at initial fitting. However, 16 of the 29 patients were using a 16 Fr.v.p. at the end of the first year, and 13 were using a 20 or 21 Fr.v.p. at the end of the first year. At the initial post-operative session, more patients used 16 Fr. v.p.s than 20 or 21 French. This reflects the surgeon's decision on tracheoesophageal puncture diameter and the initial use of the Provox 2 (21 Fr.) (See Table 4).

How many patients switch from a clinician-inserted v.p. to a patient-inserted v.p. and vice versa in the first year of recovery? At initial fitting, 27 of the 29 patients used a patient-inserted device, and only 2 of the 29 patients used a clinician-inserted device. However, while most patients continued with patient-inserted v.p.s there was a trend to increase the use of clinician-inserted devices in the first year. At the end of the first year, 22 patients used patient-inserted devices, and 7 used clinician-inserted devices (See Table 6).

Are there gender-related differences in speech rehabilitation in the first year of recovery? A reduction in length of the v.p. over the first year was evident in both males and females. The average length of v.p. at initial fitting and at the end of the first year for women was 15.11 mm and 10 mm, respectively (see Table 8). Whereas, the average length of v.p. at initial fitting and at the end of the first year for men was 16.6 mm and 11.33 mm, respectively (see Table 9).

The number of speech therapy sessions did not differ as a function of patient gender either. There were 9 females consisting of 76 total visits and 20 males consisting of 135 total visits. This amounts to approximately 8.4 visits per female and 6.75 visits per male. The patient is scheduled to see the surgeon every 6 to 8 weeks, and because many patients must travel a long distance to get to the clinic, the speech-language pathologist tries to schedule voice therapy sessions on the same day. This suggests that the patients were seen on a regular schedule.

Neither length nor speech therapy sessions differed as a function of patient gender. However, there was a difference in age among gender at the time of surgery. Females tended to be older than males at the time of surgery. The mean age of females and males at the time of surgery was 65 years and 60 years, respectively. The age of females ranged from 51 years: 1 month to 79 years: 8 months at the time of surgery, whereas the age of males ranged from 41 years: 11 months to 81 years: 6 months at the time of surgery (see table 2).

Do clinician-inserted v.p.s really last longer than patient-inserted v.p.s? As mentioned previously, the clinician-inserted v.p. is a more recent development that was created in hopes of solving self-care issues. They contain larger tracheal and esophageal

retention collars requiring a significantly greater effort to remove and replace the v.p. (Stemple, Glaze, & Klaben, 2000). Although these v.p.s are reputed to be more durable (lasting approximately 6 to 12 months), they are also more expensive (InHealth Technologies Price List, 2005) and the present data do not support the claim of increased durability, at least not durability commensurate with cost. Therefore, it would be beneficial to the patient, if the patient was aware of whether the clinician-inserted v.p. really lasts longer than the patient-inserted device.

Unfortunately, the clinician-inserted v.p. proved to have a relatively short useful life in the present study. The sample contained 89 patient-inserted and 15 clinician-inserted v.p.s. The average number of days between fittings of the clinician-inserted v.p.s was 76.7 days. The range was 14 to 220 days, the median was 62 days, and the standard deviation was 55.11 days. The average number of days between fittings of the patient-inserted v.p.s. was 55.33 days. The range was 1 to 338 days, the median was 42 days, and the standard deviation was 54.6 days (See Table 5).

However, durability is not the only issue in selecting a clinician-inserted device. A clinician-inserted device may also be selected in regards to self-care issues. The patient may not be able to remove, clean, and reinsert the device themselves for various reasons, including poor eye sight, poor fine motor skills, and hospitalization of the patient due to pneumonia or recurrent cancer, and etcetera.

There are also reasons for not selecting a clinician-inserted device. One reason is expense. As mentioned previously, clinician-inserted v.p.s are purported to last longer, thus they are more expensive. As of March 1, 2005, Inhealth's patient-inserted duckbill v.p. was only 27 dollars, and the low pressure v.p. was only 43 dollars. However,

Inhealth's clinician-inserted v.p. was 125 dollars (Inhealth Technologies Patient Price List, 2005), and as of February 1, 2005, Atos's clinician-inserted v.p. was 199 dollars (Atos Medical price list, 2005). As of 7/1/05, Medicare's reimbursement for all voice prostheses, regardless of actual cost, was \$88.09. Aetna's reimbursement was \$78.69, United Health Care's reimbursement was \$136.00, and Medical Mutual's reimbursement was \$74.00 (Billing Information on Patient Records). The cost exceeds the rate of reimbursement for clinician-inserted v.p.s.

How long do these v.p.s last before they wear out? A total of 104 v.p.s were removed and/or replaced in the 29 patients available for long-term follow-up. Thirty-three of these v.p.s were removed and replaced, because the v.p. had worn out. Of the 33 v.p.s that had worn out, 28 (27%) had been colonized with candida, and the valve broke in 5 v.p.s. The 33 v.p.s lasted an average of 76 days from fitting of the v.p. to removal due to candida colonization or a worn out valve. The range was 2 to 338 days, the median was 54 days, and the standard deviation was 71. There were 11 Bivona ultra-low resistance v.p.s, 9 Inhealth low pressure v.p.s, 4 Inhealth Indwelling v.p.s, 4 Inhealth duckbill v.p.s, 4 Atos Provox II v.p.s, and 1 Bivona duckbill v.p. that were colonized with candida. Of the 5 v.p.s with broken valves, 4 were ultra-low resistance v.p.s, and 1 was a low pressure v.p.

Are there factors in patient speech rehabilitation more commonly found following radiation? Another trend was the pervasive presence of candida colonization of voice prostheses. Past studies have recognized that it is common for patients who have had radiation treatment to colonize candida albicans on their v.p.s. In the present study, 22 of the 29 patients available for long-term follow-up also underwent radiation therapy

either before or after surgery. More specifically, 17 of the 22 patients underwent radiation therapy post-operatively, and 5 underwent radiation therapy pre-operatively. Of these 22, 10 exhibited candida on their v.p.s. However, 12 other patients who underwent radiation therapy either before or after surgery did not. Of the 10 patients who exhibited candida on their v.p.s, 8 had received radiation treatment post-operatively, and the remaining 2 had received radiation pre-operatively. Of the 12 patients who underwent radiation therapy either before or after surgery and did not exhibit candida, 9 had received radiation treatment post-operatively, and 3 had received radiation pre-operatively. Essentially 55% of the patients with radiation therapy did not colonize their v.p.s. Furthermore, of the 7 patients who did not receive radiation therapy, 3 exhibited candida colonization, and 4 did not (See Table 10).

Since radiation therapy is typically limited to the first year of recovery, but occupies a significant amount of time in that year (6 weeks of treatment and 3-6 months of recovery) this is an important factor in the first year's progress for these patients, but should not be such a factor in subsequent years. Hence, there is a need for continued study of recovery, at least into the second year. This marks the first of two limitations of the present study.

The second limitation deals with the fact that there are advanced prostheses that were not available during this study, including the Blom-Singer Indwelling Advantage & the Provox ActiValve. The Blom-Singer Indwelling Advantage is a clinician-inserted device that contains silver oxide in the silicone flap valve in order to prevent candida colonization. This device also includes an easy-fold esophageal retention flange and

flange introducer, a brush and flush cleaning system with built-in safety features, and taper-tip gel cap insertion (Inhealth Product Catalog, 2005).

The Provox ActiValve was designed to prevent excessive candida growth and to help prevent inadvertent opening. Candida is prevented due to a valve seat made of a candida resistant material, and inadvertent opening is prevented by means of magnets holding the valve and valve seat together (Atos Medical Catalog, 2005). Future studies may want to address these newer types of v.p.s.

Conclusion

Today, speech-language pathologists and otolaryngologists face a myriad of decisions when assisting the laryngectomee. These decisions greatly affect the restoration of voice and can prevent isolation and depression for the post-laryngectomy patient. Three trends that are beneficial in the clinical decision-making process were identified in the present study. These are a reduction in v.p. length over the first year, a relatively short useful life of the clinician-inserted v.p.s, and a pervasive presence of candida colonization of v.p.s. All three trends involve factors considered in the decision making process, including durability, expense and patient ability to care for the v.p.

The primary trend in the present study was a reduction in v.p. length over the first year of recovery. If voice prosthesis length dramatically decreases throughout the first year, durability should not be an issue. It would not be wise to buy a more durable device that is purported to last approximately 6 to 12 months and is more expensive, if a shorter v.p. is needed before this time frame has expired or before the more durable prosthesis has worn out. The data indicate that patients in the first year of recovery require new v.p.s not only because of eventual weakening of the valve, but more commonly because

there is a need for a shorter v.p. This raises two clinical issues: first, patients need to be seen frequently in the first year to monitor voice prosthesis length, and second, durability of the valve does not appear to offer significant value in the first year of recovery. Since there is likely to be frequent v.p. changes in the this time frame, selection of the less expensive pt. inserted devices would serve to reduce overall costs. As mentioned previously, the clinician-inserted v.p. is more expensive, and this cost exceeds the rate of reimbursement.

However, durability and expense are not the only issues in selecting or not selecting a clinician-inserted device. Clinician-inserted devices were also created in hopes of solving self-care issues. The patient may not be able to remove, clean, and reinsert the device themselves for various reasons, including poor eye sight, poor fine motor skills, and hospitalization of the patient due to pneumonia or recurrent cancer, etc. Cost, therefore, is only one factor the clinician should consider in deciding between a pt. inserted or a clinician inserted device.

The second trend in the present study was the relatively short useful life of the clinician-inserted v.p.s. As mentioned previously, a total of 104 v.p.s were removed and/or replaced in the 29 patients available for long-term follow-up. Of the 104 v.p.s, there were 15 clinician-inserted devices and 89 patient-inserted devices. The average number of days between fittings of the clinician-inserted v.p.s was 76.7 days, and the median was 62 days. The average number of days between fittings of the patient-inserted v.p.s. was 55.33 days, and the median was 42 days (See Table 5). On average the clinician-inserted v.p.s were only in place 21.37 days longer than the patient-inserted v.p.s. These v.p.s were replaced for various reasons including the presence of candida

(28), a worn out valve (5), the need for a shorter v.p. (37), the need for a longer v.p. (8), an aspirated, lost, or protruded v.p. (7), the decision to use a different type or manufacturer (9), or unknown reasons (10).

The third trend in the present study was a pervasive presence of candida colonization of v.p.s. Past studies have recognized that it is common for patients who have had radiation treatment to colonize candida albicans on their v.p.s. In the present study, 22 of the 29 patients available for long-term follow-up underwent radiation therapy either before or after surgery. However, candida was not present after radiation in just as many patients who did develop candida after radiation. More specifically, 10 developed candida after radiation, and 12 did not develop candida after radiation. Essentially, 54.5% of the patients with radiation therapy did not colonize their v.p.s. These data run counter to the expectation of some that candida colonization tends to be a complication of radiation therapy (See Table 10).

Eight of the 15 clinician-inserted devices (53.3%) and 25 of the 89 patient-inserted devices (28%) were removed and replaced either because the valve broke (Low Pressure or Ultra Low Resistance) or the valve was leaking, typically associated w/ candida colonization. Clinician-inserted devices may increase ease of patient care and the valve appeared more robust to damage; however, their useful life in the first year was shorter than anticipated. The present data demonstrated the pervasiveness of candida among these patients. Given the cost of the clinician-inserted devices and the ubiquity of candida colonization (27% overall), clinicians should give serious consideration to use of antifungal medications early in these patients' recovery, rather than waiting for premature valve breakdown.

Clinicians have had the option of tracheoesophageal puncture for voice restoration for a quarter century. While the concept is simple (coupling the pulmonary airstream to the esophagus for phonation), the application has and continues to evolve. Changes in cancer treatment, changes in technology which permits new design of valves, and patient-specific factors challenge clinicians in the successful management of patient speech rehabilitation. An important source of knowledge for clinical decision-making is the progress of the patient themselves. The present study reviewed the first year of recovery and found that the one constant was change. Clinicians should prepare their patients for this change and to base their treatment plans on the need to monitor for and control this change in order to adjust treatment to maximize success.

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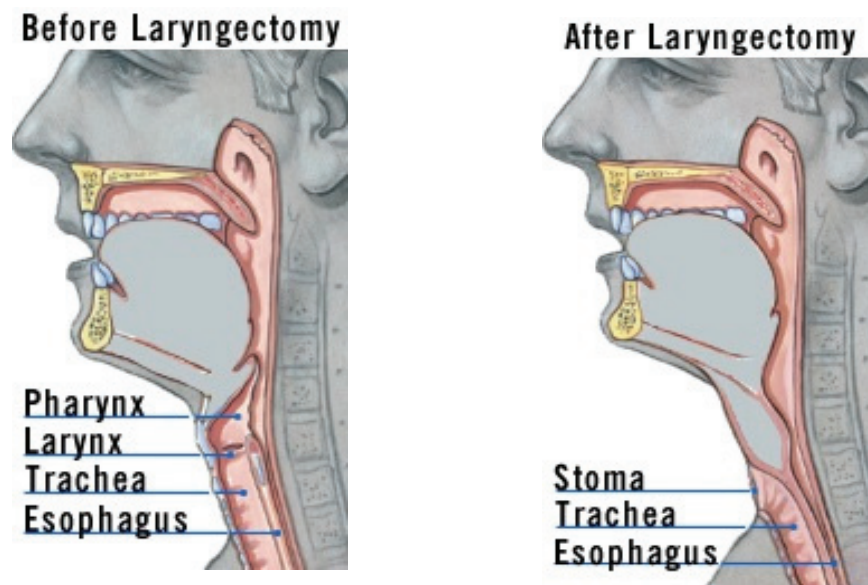
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Appendix A

Figure 1. Anatomy Before and After Total Laryngectomy

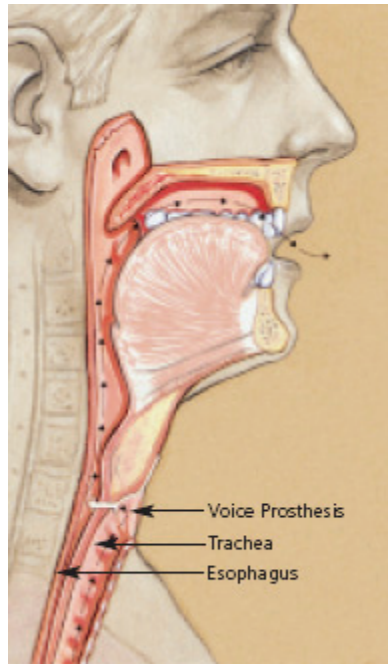
www.inhealth.com



Appendix B

Figure 2. A depiction of the direction of airflow in tracheoesophageal speech

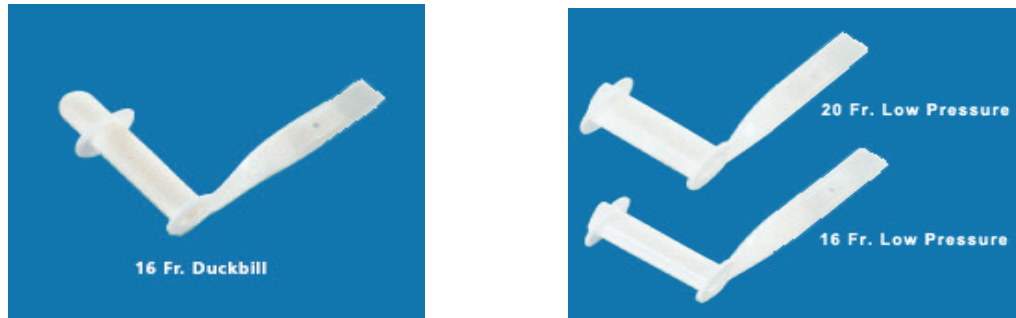
www.inhealth.com



Appendix C

Figure 3. Inhealth's Patient-Inserted Voice Prostheses

www.inhealth.com



Appendix D

Figure 4. Clinician-Inserted (Atos & Inhealth) Voice Prostheses
www.atosmedical.com



Provox 1



Provox 2



Inhealth Indwelling (www.inhealth.com)

Table 1. Voice Prostheses in the Present Study

Manufacturer	Type	Length	Diameter	Prices
Bivona	Duckbill (Patient-inserted)	8 lengths - 1.4cm to 3.3cm	16 Fr. & 20 Fr.	Ceased Manufacture in 2004
Bivona	Ultra-Low Resistance (Patient-inserted)	7 lengths – 1.4cm to 3.0cm	16 Fr. & 20 Fr.	Ceased Manufacture in 2004
Inhealth	Duckbill (Patient-inserted)	9 lengths – 6mm to 28mm	16 Fr.	\$27.00 as of March 1, 2005
Inhealth	Low-Pressure (Patient-inserted)	9 lengths – 6mm to 28mm	16 Fr. & 20 Fr.	\$43.00 as of March 1, 2005
Inhealth	Indwelling (Clinician-inserted)	8 lengths – 6mm to 25mm	16 Fr. & 20 Fr.	\$125.00 as of March 1, 2005
Atos	Provox (Clinician-inserted)	5 lengths – 4.5mm to 12.5mm	21 Fr.	\$199.00 as of February 1, 2005

Table 2. Subjects by Age and Gender

	Mean Age (Years)	Range (Years: Months)
Males (20)	60 Years	41:11 to 81:6
Females (9)	65 Years	51:1 to 79:8

* Females tended to be older than Males at time of surgery

Table 3. Prosthesis Length at Initial Fitting & After 12 months

	Average Length	Range	Mode	Standard Deviation
Initial Fitting	16.28 mm	8 mm to 28 mm	18 mm	4.68 mm
12 Months	10.91 mm	4.5 mm to 18 mm	10 mm	3.2 mm

*There was a strong tendency for refitting with a shorter v.p. over the course of the first year.

Table 4. Prosthesis Diameter at Initial Fitting & End of 1st Year

	16 French	20 (21) French
Initial Fitting	25	4
End of First Year	16	13

*At the initial post-operative session, more pts. used 16 Fr. v.p.s than 20 Fr. This reflects the surgeons' decision on tracheoesophageal puncture diameter and the initial use of the Provox 2 (21Fr.).

Table 5. Clinician-Inserted vs. Patient-Inserted # of days between fittings

	# of v.p.	Average	Range	Median	Standard Deviation
Clinician-Inserted	15	76.7 days	14 to 220 days	62 days	55.11 days
Patient-inserted	89	55.33 days	1 to 338 days	42 days	54.6 days

Table 6. Clinician-Inserted vs. Patient-Inserted at Initial Fitting

	Initial Fitting	First Year
Clinician-Inserted	2	7
Patient-Inserted	27	22

While most pts. continued with Patient-Inserted v.p.s there was a trend to increase the use of clinician inserted devices in the first year.

Table 7. Number of Days between Fitting of VP and Removal due to Candida colonization

	# of VP w/ Candida	Mean	Range	Standard Deviation
Inhealth Duckbill	4 of 10 (40%)	121.25	21 to 338	147.387
Inhealth Low Pressure	8 of 46 (17%)	56.75	7 to 183	62.56
Inhealth Indwelling (Clinician-inserted)	4 of 10 (40%)	84	14 to 220	92.76
Bivona Duckbill	1 of 11 (9%)		21	
Bivona Ultra-Low Resistance	7 of 22 (32%)	71.86	28 to 147	41.78
Atos Provox (Clinician-inserted)	4 of 5 (80%)	90.25	47 to 156	47.95

Table 8. Prosthesis Length at Initial Fitting & After 12 months—Female Pts.

	Average Length	Range	Mode	Standard Deviation
Initial Fitting	15.11 mm	8 to 22 mm	18mm	4.26 mm
12 Months	10 mm	8 to 14 mm	8 mm	2.45 mm

Table 9. Prosthesis Length at Initial Fitting & After 12 months—Male Pts.

	Average Length	Range	Mode	Standard Deviation
Initial Fitting	16.6 mm	8 to 28 mm	18 mm	4.73 mm
12 Months	11.33 mm	4.5 to 18 mm	10 mm	3.46 mm

Table 10. Frequency with which Candida Colonization Co-occurred with Radiation Therapy

	Candida	No Candida
Radiation	10	12
No Radiation	3	4

*These data run counter to the expectation of some that candida colonization tends to be a complication of radiation therapy.